

AMENDMENTS TO THE CLAIMS

1. (original) A pharmaceutical composition comprising:
 - a therapeutically effective amount of a drug;
 - a solubilizer;
 - and a release modulator;
 - wherein the release of the drug and solubilizer are synchronized.
2. (original) The pharmaceutical composition of claim 1, wherein the drug is pioglitazone, zafirlukast, simvastatin, atorvastatin or fenofibrate.
3. (currently amended) The pharmaceutical composition of claim 1, wherein the solubilizer is a polyoxyethylene-polyoxypropylene block copolymer, a polysaccharide-based polymereyelodextrin or cyclodextrin derivative, a ~~fatt~~fatty acid or fatty acid ~~derivative~~ester, a tocol, ~~derivative~~ or mixtures thereof.
4. (currently amended) The pharmaceutical composition of claim 3, wherein the tocol is a tocol derivative ~~is selected from the group consisting of~~ a α -tocopherol ester, a polyethoxylated α -tocopherol ester, racemers, enantiomers, or mixtures thereof.
5. (currently amended) The pharmaceutical composition of claim 3, wherein the tocol is a tocol derivative ~~is selected from the group consisting of~~ α -tocopherol, α -tocopherol acetate, α -tocopherol ~~niotin~~nicotinate, α -tocopherol succinate, α -tocopherol polyethyleneglycol succinate, α -tocopherol polyethyleneglycol (200-8000) succinate, α -tocopherol

polyethyleneglycol 400 succinate, α -tocopherol polyethylene glycol 1000 succinate, d- α -tocopherol polyethylene glycol 1000 succinate, dl- α -tocopherol polyethylene glycol 1000 succinate, racemers, enantiomers, or mixtures thereof.

6. (currently amended) The pharmaceutical composition of claim 3, wherein the fatty acid derivative is an ester with glycerol, propylene glycol, sorbitol, sucrose, glucose, polyethylene glycol, an alpha-hydroxy acid or mixtures thereof.

7. (currently amended) The pharmaceutical composition of claim 3, wherein the fatty acid ester is a polyoxyl castor oil derivative, a PEG-8 caprylic/capric glyceride, a polysorbate, sorbitan monooleate, a medium chain mono-, di-, or triglyceride, a acetylated monoglyceride, a linoleoyl monoglyceride, a lauroyl macrogol-32 glyceride or mixtures thereof.

8. (currently amended) The pharmaceutical composition of claim 1, wherein the release modulator is an osmotic pump, a slowly dissolving salt of a complex, an erodible matrix, an ion exchange resin, a wax, an insoluble carrier, a polymeric matrix, a polymeric coating, a fatty alcohol, ~~a fatty alcohol derivative, a fatty acid or fatty acid derivative~~, a tocol, ~~derivative~~ racemers, enantiomers, or mixtures thereof.

9. (currently amended) The pharmaceutical composition of claim 8, wherein the release modulator is a polymeric matrix, a polymeric coating, a wax, a fatty alcohol, ~~a fatty alcohol derivative, a fatty acid or fatty acid derivative~~, a tocol, ~~derivative~~ racemers, enantiomers, or mixtures thereof.

10. (currently amended) The pharmaceutical composition of claim 9, wherein the polymeric matrix or polymeric coating is a cellulose-~~derivative~~, an acrylic polymer, a polyvinylpyrrolidone copolymer, a shellac, polyvinyl acetyl phthalate, a ~~high molecular weight~~ polysaccharide gum or mixtures thereof.

11. (currently amended) The pharmaceutical composition of claim 9, wherein the tocol is a tocol derivative is selected from the group consisting of α -tocopherol, α -tocopherol acetate, α -tocopherol ~~nicotinate~~ nicotinate, α -tocopherol succinate, α -tocopherol polyethyleneglycol succinate, α -tocopherol polyethylene glycol 400 succinate, racemers, enantiomers, or mixtures thereof.

12. (original) The pharmaceutical composition of claim 8, wherein the release modulator is hydrogenated vegetable oil, glycerol dibehenate, glycerol distearate, glycerol dipalmitate, glycerol palmitostearate, lauroyl macrogol-32 glyceride, stearyl macrogol-32 glyceride, calcium steroyl lactylate, stearic acid, stearyl alcohol, sucrose distearate, sucrose palmitate, sucrose dipalmitate, yellow wax, white wax, nonionic emulsifying wax, carnauba wax, microcrystalline wax, cetyl ester wax or mixtures thereof.

13. (original) The pharmaceutical composition of claim 1, wherein the aqueous solubility of the drug is less than about 100 $\mu\text{g/ml}$.

14. (original) The pharmaceutical composition of claim 1, wherein the aqueous solubility of the drug is less than about 50 $\mu\text{g/ml}$.

15. (original) The pharmaceutical composition of claim 1, wherein the aqueous solubility of the drug is less than about 25 $\mu\text{g/ml}$.

16. (original) The pharmaceutical composition of claim 1, wherein the release is over an extended period of time.

17. (original) The pharmaceutical composition of claim 1, wherein the period of time is more than about 1 hour.

18. (original) The pharmaceutical composition of claim 1, wherein the period of time is more than about 2 hours.

19. (currently amended) The pharmaceutical composition of claim 1, wherein the period of time is ~~between~~from about 2 hours ~~and to~~ about 24 hours.

20. (original) The pharmaceutical composition of claim 1, wherein the solubilizer increases the solubility of the drug by at least 25% in comparison to the intrinsic aqueous solubility of the drug.

21. (original) The pharmaceutical composition of claim 1, wherein the release of the drug and solubilizer are synchronized with a correlation coefficient of greater than 0.80.
22. (original) The pharmaceutical composition of claim 1, wherein the release of the drug and solubilizer are synchronized with a correlation coefficient of greater than 0.90.
23. (original) The pharmaceutical composition of claim 1, wherein the release of the drug and solubilizer are synchronized with a correlation coefficient of greater than 0.95.
24. (original) The pharmaceutical composition of claim 1 including one or more additives.
25. (original) The pharmaceutical composition of claim 1, wherein the solubilizer is d- α -tocopherol polyethylene glycol 1000 succinate or polyoxyl 40 hydrogenated castor oil and the release modulator is α -tocopherol succinate, glycerol dibehenate or hydroxypropylmethylcellulose.
26. (original) The pharmaceutical composition of claim 25, including one or more additives.
27. (original) The pharmaceutical composition of claim 26, wherein the solubilizer is d- α -tocopherol polyethylene glycol 1000 succinate, the release modulator is α -tocopherol succinate and the additive is polyethylene glycol.

28. (original) The pharmaceutical composition of claim 26, wherein the solubilizer is polyoxyl 40 hydrogenated castor oil and the release modulator is hydroxypropylmethylcellulose.
29. (original) The pharmaceutical composition of claim 1, wherein the aqueous solubility of the drug is dependent on pH.
30. (original) The pharmaceutical composition of claim 29, wherein the drug has a pK_a of less than or equal to about 9.0.
31. (original) The pharmaceutical composition of claim 30, wherein the drug is carvedilol, amiodarone, dronedarone, risperidone or ziprasidone.
32. (original) A oral dosage form comprising: a therapeutically effective amount of a drug; a solubilizer; and a release modulator; wherein the release of the drug and solubilizer are synchronized.
33. (original) A solid oral dosage form comprising: a therapeutically effective amount of a drug; a solubilizer; and a release modulator; wherein the release of the drug and solubilizer are synchronized.
34. (new) The pharmaceutical composition of claim 3, wherein the polysaccharide-based polymer is selected from the group consisting of maltodextrins, dextrates, cyclodextrins, and mixtures thereof.

35. (new) The pharmaceutical composition of claim 34, wherein the polysaccharide-based polymer is a cyclodextrin.

36. (new) The pharmaceutical composition of claim 35, wherein the cyclodextrin is a cyclodextrin derivative selected from the group consisting of sulfobutyl ethers, hydroxypropyl ethers, and mixtures thereof.